

REMARKS

In response to the Office Action mailed September 3, 2009, Applicants respectfully request reconsideration. Claims 1-43, 74 and 95 were previously pending in this application, with claims 11, 16-43, 74 and 95 being withdrawn from consideration. By this amendment, claims 1, 8, 10 and 13 are being amended. Claim 12 is being canceled without prejudice or disclaimer. No claims are being added. As a result, claims 1-10 and 13-15 are pending for examination with claim 1 being independent. No new matter has been added.

Election of Species Requirement

Applicant affirms the election of species presented in paragraph 2 of the Office Action mailed on September 3, 2009. Pending claims 1-10 and 13-15 are believed to represent a grouping representative of the elected species.

Applicant expressly reserves the right to pursue subject matter of the non-elected claims in one or more continuation and/or divisional applications.

Claim Objection

Claim 15 was objected to because “nitinol” was not capitalized. Claim 15 is being amended herein to capitalize the word Nitinol. Withdrawal of the objection to claim 15 is respectfully requested.

Rejections under 35 U.S.C. §112

Claims 8, 10 and 13 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action contends that the term “approximately” renders each claim indefinite.

Without acceding to the propriety of the rejection, each of claims 8, 10 and 13 has been amended to delete the term “approximately”. Accordingly, withdrawal of the rejection of each of claims 8, 10 and 13 under 35 U.S.C. §112 is respectfully requested.

Rejections Under 35 U.S.C. §103

The Office Action rejected claims 1-10 and 14 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,755,760 to Maguire et al. (hereinafter, “Maguire”) in view of U.S. Patent No. 5,938,694 to Jaraczewski et al. (hereinafter, “Jaraczewski”).

Claim 1 recites, among other limitations, a tip assembly including a wire formed of a superelastic material and shaped to bias the tip assembly in a first orientation. Claim 1 further recites a cable attached to the tip assembly. The cable is adapted to change an orientation of the tip assembly from the first orientation in response to movement of an actuator.

The Office Action points to distal tip (602) of Figure 12a of Maguire as a tip assembly. The Office Action notes that Maguire fails to disclose the tip assembly including a wire formed of a superelastic material and shaped to bias the tip assembly in a first orientation. According to the Office Action, “[a]t the time of the invention, it would have been obvious to one of ordinary skill in the art to use a superelastic spring material because it is very resilient and has a good spring memory for its prior shape, even when highly flexed as taught by Jaraczewski et al. (Column 5, Lines 24-25).”

While the Office Action addresses the use of a superelastic material, the Office Action does not provide a rationale as to why it would be obvious to one of ordinary skill in the art to bias the tip assembly of Maguire in a first orientation with a shaped wire. As amended, claim 1 recites that the tip assembly includes a wire shaped to bias the tip assembly in a first orientation including a curved shape. Claim 1 further recites a cable attached to the tip assembly, the cable being adapted to change an orientation of the tip assembly from the first orientation. Maguire does not disclose the combination of: a wire which is shaped to bias the tip assembly in a first orientation including a curved shape; and a cable that is adapted to change the orientation of the tip assembly from the first orientation. A rationale as to why it would have been obvious to one of ordinary skill in the art to combine the shaped core (14) of Jaraczewski with the deflectable catheter embodiment of Maguire is lacking in the Office Action. For at least this reason, withdrawal of the rejection of claim 1 is respectfully requested.

Additionally, the Maguire and Jaraczewski references must be considered in their entireties, and one of ordinary skill in the art would be lead away from using the shaped cores (14) of Jaraczewski in the deflectable catheters of Maguire. Maguire describes a catheter including a combination of features which allows for the catheter to be deflected into a multiplicity of configurations (see column 7, lines 1-4 of Maguire). Conversely, the distal end of the catheter in Jaraczewski is disclosed to have only one of four distinct shapes by way of a shaped core (14) (see Figures 1-2c and column 5, lines 28-37 of Jaraczewski). Each of the four shapes shown in Jaraczewski has either a tortuous path or several complete revolutions around the longitudinal direction of the catheter. It is not clear from Maguire's disclosure that the deflection cables of Maguire could move the complex, precurved distal tip arrangements of Jaraczewski in a controlled, predictable manner.

As a further indication that one of ordinary skill in the art would be lead away from combining the shaped core wire of Jaraczewski with the deflectable device of Maguire, Maguire explicitly mentions a distinct embodiment in which a preformed catheter body is used, yet does not state that such a preformed catheter body could be used in combination with a deflectable catheter. In fact, Maguire goes on to state that the preformed catheter body embodiment could be used with the deflectable guide catheter, but again fails to even simply mention that the preformed catheter body could be used in combination with the deflectable catheter. If including a preformed catheter body section in a deflectable catheter section were obvious to one of ordinary skill in the art, Maguire would have at least mentioned the possibility in view of the other disclosures in Maguire.

Each of claims 2-10 and 11-15 depends either directly or indirectly from claim 1, and withdrawal of the rejections of these claims is respectfully requested for at least the same reasons provided above for claim 1.

Dependent Claims

Regarding dependent claims 3, 6 and 9, the Office Action states that including the features of each of these claims would have been a matter of obvious design choice because the applicant has not disclosed that each feature solves any stated problem or is for any particular purpose. As outlined in the introduction to MPEP §2143, the key to supporting any rejection under 35 U.S.C.

§103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The burden is on the Examiner to present a *prima facie* case for obviousness as opposed to the applicant presenting a position as to non-obviousness. In the case of each of claims 3, 6 and 9, the burden is on the Examiner to explain why, in view of the prior art, the combination of features of each claim (including each claim's base claim and any intervening claims) is a matter of design choice. For at least this additional reason, withdrawal of the rejections of claims 3, 6 and 9 is respectfully requested.

CONCLUSION

It is respectfully believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment set forth in the Office Action does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Furthermore, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify any concession of unpatentability of the claim prior to its amendment.

If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicants' representative at the telephone number indicated below to discuss any outstanding issues relating to the allowability of the application.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 23/2825 under Docket No. B1075.70032US00 from which the undersigned is authorized to draw.

Dated: November 30, 2009

Respectfully submitted,

By _____

Eric L. Amundsen
Registration No.: 46,518
WOLF, GREENFIELD & SACKS, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
617.646.8000